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REMARKS

The present amendment is intended to be fully responsive to the Office Action having a mailing date of October 18, 2006, wherein claims 1-49 have been rejected and are currently pending. By this amendment, claims 1, 5, 7, 9, 13, 14, 16-17, 19-21, 23, 26, 33-34, and 36-39 have been amended and claims 3, 12, 18, 22, 35, and 43-49 have been canceled. Applicant has added new claim 50. Thus, claims 1-2, 4-11, 13-17, 19-21, 23-34, 36-42, and 50 remain pending. Applicant submits that no new matter has been added by this amendment and that support for the claims, as amended, may be found throughout the specification and drawings. At least for the reasons set forth below, Applicant respectfully traverses the foregoing rejections. Further, Applicant believes that there are also reasons other than those set forth below why the pending claims are patentable, and reserve the right to set forth those reasons, and to argue for the patentability of claims not explicitly addressed herein, in future papers. Applicants respectfully requests reconsideration of the present application in view of the above amendment, the new claims, and the following remarks.

Claim Objections

Claims 33 and 34 were objected to under 37 CFR 1.75(c), as being improper dependent form. Applicants have corrected claims 33 and 34, as suggested by the Examiner. Withdrawal of the objection is therefore requested.

35 U.S.C. §112

Claim 19 was rejected under 35 U.S.C. §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner has stated that the term "relatively low artifact generating" is not defined. Applicant respectfully traverses the rejection and respectfully points the Examiner to paragraph [0025] where the term is defined. However, Applicants have also amended claim 19 to further clarify the scope of the invention defined by claim 19. Withdrawal of the rejection is therefore respectfully requested.

35 U.S.C. § 102

Claim Rejections Using *Werne*

Claims 1-14 and 18-49 are rejected under 35 U.S.C. § 102(b) as being anticipated by *Werne* (U.S. Patent No. 5,782,764). Applicants respectfully traverse the rejection.

Independent claim 1, as amended, recites a cannula that has open distal and proximal ends and an introducer stylet. The introducer stylet is slidable within a lumen of the cannula. Further, the stylet has a length that is substantially longer than a length of the cannula such that when the stylet is positioned within the cannula, the distal end of the stylet extends a substantial distance from the distal end of the cannula. After the introducer stylet is removed from the cannula, a target confirmation device is inserted into the cannula such that a distal end of the target confirmation device extends outwardly from the distal end of the cannula.

In contrast to Applicants' invention, as defined by Claim 1, *Werne* discloses a thrusting biopsy needle 140 that receives a marking stylet 142. Unlike in Applicants' invention, as defined in amended Claim 1, the marking stylet 142 in *Werne* and cannula are fixedly attached together *and are advanced in a distal direction into a target*. See, col. 11, lines 35-38. In contrast to *Werne*, the introducer stylet of claim 1 is slidable relative to the cannula. For at least this reason, Claim 1, as amended, is patentably distinct from *Werne*.

Werne also discloses that the tip 142A of the marking stylet 142 extends only slightly away from the distal end of the biopsy needle. Further, the contrast agent 146 in the marking stylet 142 is positioned within the biopsy needle. In contrast to Werne, Claim 1, as amended, the claimed introducer stylet is sized so as to be substantially longer than the cannula. Accordingly, when the introducer stylet is positioned within the cannula the distal end of the introducer stylet extends substantially past the distal end of the cannula. Thus, as this feature is clearly not shown, for this separate reason, Claim 1, as amended, is patentably distinct from Werne.

Further, Claim 1, as amended, requires a separate target confirmation device. The target confirmation device is insertable within the cannula when the introducer is removed. This feature is also not shown in Werne. Moreover, the distal end of the claimed target confirmation device extends substantially outwardly from the distal end of the cannula. This feature is clearly not shown in Werne. Indeed, Werne discloses contrast agent that is disposed within the biopsy device. For this additional separate reason, Claim 1, as amended, is patentably distinct from Werne.

Claims 2, 4-6, 13, 14, 19-21, 23-25, 33, and 35-40 are dependent upon claim 1. Thus, because claim 1 is patentable over Werne (as demonstrated above), these claims also define over Werne. Further, these claims have additional limitations that are also distinguishable from Werne. For example, claim 5 recites that a band of MRI identifiable material is disposed proximate a distal end of the target confirmation device so as to extend distally of the distal end of the cannula. This feature is clearly not taught or shown in Werne. Further, claim 14 recites that the outer cannula includes a fluid conduit for delivering fluid to the conduit that is in communication with the lumen of the cannula. This feature is not taught or suggested by Werne. Instead, Werne merely teaches an inner obtruator 50 that is has an opening 52 that aligns with an opening 48 in the biopsy needle 40. Werne certainly does not teach or even suggest delivering fluid through the biopsy needle 40 via the inner obtruator.

Independent Claim 7, as amended, recites a cannula that has a first length and an introducer stylet that has a second length that is longer than the first length. Thus, when the introducer stylet is disposed within the cannula and slid therein, the distal end of the introducer stylet extends substantially away from the distal end of the cannula. This feature is not shown in Werne. Indeed, Werne teaches a marking stylet that is fixed to the biopsy needle such that only a small portion of the marking stylet extends distally from the biopsy needle.

Further, claim 7 also requires a separate target confirmation device that has a length that is substantially longer than the length of the cannula such that a distal end of the target confirmation device (including imaging material) extends substantially outwardly from the distal end of the cannula. This feature is also not taught by Werne as Werne only teaches a single marking stylet.

Further, the marking element of the marking stylet taught in Werne is contained within the biopsy needle, unlike the claimed invention of claim 7. Accordingly, for these separate reasons, claim 7 defines over Werne.

Claims 8-11 and 34 are dependent upon claim 7. Thus, because claim 7 is patentable over Werne (as demonstrated above), these claims also define over Werne. Further, these claims have additional limitations that are also distinguishable from Werne. For example, claim 9 recites that a distal end of the target confirmation device has a predetermined shape so as to distinguish the target confirmation device from the patient's tissue. This feature is also not taught or shown in Werne.

Independent Claim 26, as amended, recites a medical procedure that includes inserting an introducer stylet into an outer cannula such that a distal end of the introducer stylet extends substantially outwardly from a distal end of the outer cannula, inserting the stylet and outer cannula into a patient's tissue, removing the introducer stylet from the patient's body, and then, inserting a separate target confirmation device through the outer cannula such that the distal end of the target confirmation device extends substantially outwardly from a distal end of the cannula.

Werne, in contrast, teaches simply placing a marking stylet into a biopsy needle such that the distal end of the marking stylet is only slightly extended from the distal end of the marking stylet. Nor does Werne teach removing the introducer stylet from the patient's body and then inserting a separate target confirmation device. Accordingly, claim 26, as amended, is patentably distinct from Werne.

Claims 27-32 and 41-42 are patentably over Werne due to their dependency upon claim 26.

Based on the foregoing, claims 1-2, 4-11, 13-14, 19-21, 23-42 are in condition for allowance. Applicant therefore respectfully requests withdrawal of the rejection.

35 U.S.C. § 103

Claim Rejections Using *Werne* in view of *Laird*

Claims 15-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Werne* ('764) in view of *Laird* (U.S. Patent No. 6,276,661). Applicants respectfully traverse the rejection.

First and foremost, the discussion above in connection with the 102 rejection is equally applicable here. For example, the inadequacy of *Werne* to teach every element of independent claim 1 (from which claims 15-17 depend) by not teaching an introducer stylet that is slidable relative to a cannula, is fatal to the Examiners §103 rejection. Additionally, *Laird* does not teach this feature, and therefore, cannot make up for the inadequacy described above. Therefore, the combination of *Werne* and *Laird* does not teach every limitation of independent claim 1, as required in *In re Royka*. Furthermore, dependent claims 15-17, being dependent upon independent claim 1, are patentable by being dependent on an allowable base claim. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Further, MPEP Section 2143 states as follows: "To establish a prima facia case of obviousness, three criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." However, "[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In this case, the Examiner has admitted that *Werne* certainly provides no suggestion or motivation to make the combination. Indeed, the Examiner has affirmatively concluded that *Werne* is "silent" regarding use of "a valve" in the system. Further, the Examiner has also engaged in impermissible hindsight in making the combination. For example, the Examiner has not pointed to

the prior art to establish the required suggestion or desirability of the combination. Instead, the Examiner has simply concluded that a pressure-actuated introducer valve is "equivalent to a direction valve *and* a hemostatic valve" disclosed in *Laird*. However, as is clear, the directional valve and the hemostatic valve disclosed and claimed in Applicants' claims 15 and 17, respectively, are two different valves serving different functions. Indeed, the directional valve claimed in claim 15 is attached to a fluid conduit, a feature that is clearly not shown in either *Werne* or *Laird*.

Further, while claim 16 was rejected under the *Werne/Laird* combination, the Examiner has failed to illustrate where in either *Werne* or *Laird* the claimed limitations are found. Applicants have reviewed both references and have not located any disclosure of a target confirmation device having a first fitting interface that engages a second fitting interface on the outer cannula upon insertion of the target confirmation device into the outer cannula as positively claimed in claim 16.

Accordingly, for at least the reasons stated above, claims 15-17 are also believed to define over the art. Withdrawal of the rejections are therefore respectfully requested.

CONCLUSION

Reconsideration and allowance are respectfully requested. In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Any fee that is due with this response is identified in an accompanying fee transmittal. If any additional fees are due, please charge our Deposit Account No. 18-0013, under Order No. 65937-0037 from which the undersigned is authorized to draw. To the extent necessary, a petition for extension of time under 37 C.F.R. § 1.136 is hereby made, the fee for which should be charged to such deposit account number.

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Amendment dated January 18, 2007
Reply to Office Action of October 18, 2006

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Respectfully submitted,

By _____

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